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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/909,088	07/18/2001	Avi Ashkenazi	P1618P2C79	1981

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EXAMINER

ANDRES, JANET L

ART UNIT

PAPER NUMBER

1646

DATE MAILED: 04/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

### Application No.

09/909,088

### Applicant(s)

ASHKENAZI ET AL.

### Examiner

Janet L. Andres

### Art Unit

1646

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 39-47, 49-52 and 55-58 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 39-47, 49-52 and 55-58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **RESPONSE TO AMENDMENT**

1. Applicant's amendment filed 2 March 2004 is acknowledged. Claims 39-47, 49-52, and 55-58 are pending and under examination in this office action. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections Maintained***

2. The rejection of claims 39-47, 49-52, and 55-58 under 35 U.S.C. 112, first paragraph, as lacking enablement is maintained for reasons of record in the office action of 19 December 2003.

Applicant argues that experimentation is not necessarily undue and that the art of immunotherapeutics as a whole is not unpredictable. Applicant further argues that the MLR assay is widely used as a standard assay for immunomodulators. Applicant further argues that it would be routine to carry out *in vivo* experimentation to determine whether PRO335 or its antagonists are useful as immunomodulators.

Applicant's arguments have been fully considered but have not been found to be persuasive. While some experimentation need not be undue if there is an expectation of success, such an expectation is lacking for the instant invention. Activation of a mixed lymphocyte reaction is not widely used as an assay for immunotherapeutics. As was stated in the previous office action, it is widely used for determining histocompatibility, not for identifying therapeutic immunostimulatory agents. That a compound that stimulates this reaction might be of interest for study does not serve to enable its use. That it would be routine to carry out the experiments required to determine whether it could successfully be used *in vivo* is not sufficient to predict that it could in fact be used as a therapeutic agent. Applicant has provided no guidance beyond a preliminary assay to suggest that the protein could be used as a therapeutic agent or that it could

Art Unit: 1646

be a useful target for other agents. The ability of the artisan to undertake routine assays is not adequate guidance as to what those assays will indicate and thus as to whether the protein could in fact be used as taught in the specification, but is merely an invitation to the artisan to use the current invention as a starting point for further experimentation.

What is provided is thus the idea for an invention, and the invitation to experiment to implement this invention, not the invention itself.

The rejection of claims 39-47, 49-52, and 55-58 under 35 U.S.C. 112, first paragraph, as lacking written description of and enablement for variants is maintained for reasons of record in the previous office action.

Applicant argues that a functional limitation is provided. Applicant further argues that the disclosed leucine-rich repeats provide a conserved structural element.

Applicant's arguments have been fully considered but have not been found to be persuasive. As stated previously and above, the limitation that it the proteins stimulate a mixed lymphocyte reaction is not indicative of any particular function. There is no specific biochemical process implicated in this reaction: it can be effected in a variety of ways. Regardless of the skill of the artisan in performing the assay, the assay itself is not specific to any particular activity. Thus stimulation of an MLR does not require a common function. Similarly, leucine-rich repeats are not indicative of any particular function; they are found in proteins having many different functions, as is indicated by Applicant on p. 31 of the specification.

NO CLAIM IS ALLOWED.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Andres whose telephone number is 571-272-0867. The examiner can normally be reached on Monday-Thursday and every other Friday, 8:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on 571-272-0871. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Andres, Ph.D.  
20 April 2004



JANET ANDRES  
PATENT EXAMINER